CHAPTER 4

EXPOSURE ASSESSMENT STRATEGIES

1. **INTRODUCTION**. This chapter outlines the process for assessing occupational exposures. Although exposure assessments are more commonly conducted for chemical stressors, exposure assessment is equally applicable to physical stressors. When exposures and processes are stable, sufficient exposure monitoring results may be obtained to allow statistical analysis to assist in exposure assessment. However, in many Navy processes exposure monitoring opportunities may be too infrequent or the process may be too variable to allow collection of a statistically valid number of measurements. In such cases, the industrial hygienist must exercise sound professional judgment, after considering the available information, and make an exposure assessment with a well documented rationale. Exposure assessment is part of the industrial hygiene survey process and although the scope of a survey may be limited, exposure assessment strategies should not normally be applied independent of a survey. The strategy presented here is based on the strategy presented in reference 4-2 but is not identical to it. One of the major advantages of this strategy is to reduce the number of samples required for decision-making by:

a. Recognizing that SEGs with low exposure estimates (i.e., $UTL_{95\%,95\%}$ = 50% of the OEL) of high certainty do not merit sampling just to document negative exposures;

b. Recognizing that SEGs with exposures estimated to significantly exceed the OEL may be controlled without additional sampling; and

c. Recognizing that 6 to 10 samples may be sufficient to characterize many exposures, which is a significant reduction from the 11 to 29 samples recommended in previous sampling strategies.

2. **DEFINITIONS**.

a. 8-hour Time-Weighted Average (TWA)/8-hour TWA-OEL. The time weighted average concentration for a normal 8-hour workday and a 40-hour work week which cannot be exceeded. It is accepted to be a concentration to which nearly all workers may be repeatedly exposed, day after day, without adverse ef-

fects.The average level of a stressor over a specified time period weighted for the length of time at each measured level. The measurement is usually a concentration of a chemical contaminant or a level of a physical agent (e.g., noise). The duration of the TWA must be specified. The most common industrial hygiene TWA duration is 8 hours which is the length of the most common work day. A TWA may be determined by a single sample (i.e., the averaging is done by the sampling device throughout the sampled period) or by mathematical combination of one or more consecutive samples.

b. Ceiling (C)-OEL. A contaminant concentration that should not be exceeded during any part of the working exposure. If instantaneous monitoring is not feasible, samples are collected and assessed as a 15-minute time-weighted average exposure which should not exceed the Ceiling Value at any time during the working day.

c. Censoring - The process of adjusting data that is recorded as "less than" the laboratory's analytical limit of detection (LOD) for a stressor. Several methods exist for adjusting such values with the best method depending on the parameters of the distribution of the data. Currently, IHIMS adjusts all such values by dividing by the square root of 2.

d. Exceedance Fraction. The exceedance fraction is the fraction of the exposure distribution above the OEL. It is also called the probability of noncompliance.

e. Exposure Monitoring Priority. A numerical rating from 0 to 32 that describes the priority for conducting additional exposure monitoring. It is obtained by multiplying the Health Risk Rating by the Uncertainty Rating. A higher number represents a higher priority for exposure monitoring.

f. Exposure profile. An exposure profile is a characterization of the day-to-day variability of exposures of a SEG. A qualitative exposure profile may be based on professional judgment, whereas a quantitative exposure profile is based on statistics and includes measures of central tendency and measures of variability.

g. Exposure Rating. An exposure rating is an estimate of exposure level relative to an OEL. The rating is divided into four to five categories ranging from 0 or 1 to 4 with exposure ratings of 0 or 1 being the lowest and ratings of 4 being the highest. Several organizations (e.g., National Fire Protection Association, National Paint and Coatings Association)

have defined ratings systems and various systems are discussed in paragraph 7.b of this chapter.

h. Geometric Standard Deviation (GSD). The standard deviation for a log-normal distribution.

i. Health Effect Rating. Numerical category, with a scale from 0 to 4, assigned to a stressor based on considering the conditions of use. Zero represents the least effect and 4 the greatest effect.

j. Health Risk Rating. A numerical rating ranging from 0 to 16 that is obtained by multiplying the Exposure Rating times the Health Effect Rating. It is used to prioritize exposures for action.

k. Long-Term Average (LTA)-OEL. An occupational exposure limit with an averaging time of at least a week or more, that is intended to protect against chronic effects.

l. Minimum Variance Unbiased Estimate (MVUE). Air contaminant sampling data for a SEG is usually lognormally distributed. The best estimate of average exposure for a log-normal distribution is the arithmetic mean, not the geometric mean as is commonly believed. The MVUE is the preferred estimate of the arithmetic mean of a lognormal distribution.

m. Occupational Exposure Limit (OEL). An OEL is the term used to describe the limit to which the exposure profile is compared to determine if exposures are acceptable or unacceptable. OELs may be classified as one or more of the following: (1) regulatory (e.g. Navy, OSHA); (2) authoritative (e.g., ACGIH TLVs®, AIHA WEELs®, NIOSH RELs); (3) internal; or (4) working. An exposure assessment cannot be made without an OEL. Based on the hierarchy establised in Chapter 8 of OPNAVINST 5100.23 Series, Navy OELs may be drawn from many of these sources.

n. Operation Code (OP Code) - Codes that identify standard work operations/processes commonly performed in the Navy. OP Codes are used in the Navy's Industrial Hygiene Information Management System (IHIMS) for data entry and retrieval. A list of the current OP Codes is provided in Appendix 3-A of this manual.

o. Percentile (%ile). The percentage of values in a population that are below a given value. For example, if exactly 90% of all zinc oxide fume exposures from a particular

welding process are less than 4 mg/M^3, then 4 mg/M^3 is the 90 percentile (90%ile) exposure level for zinc oxide fume from that process.

p. Probability of non-compliance - See exceedance fraction.

q. Short-Term Exposure Limit (STEL)-OEL. A 15-minute TWA exposure that should not be exceeded at any time during the workday. The STEL is usually not an independent exposure limit, but rather supplements the 8-hour TWA in cases where there are recognized acute effects from a substance whose toxic effects are primarily chronic.

r. Similar exposure group (SEG). A group of employees who experience such similar exposures to stressors, that if one of the employees were monitored, the results of the monitoring could be used to predict the exposures of the remaining members of the group. Individuals within the group generally conduct the same work processes, use the same equipment, have the same job description, and are exposed to the same stressors at similar frequencies and durations. For Navy use, the initial definition of a SEG should be a combination of an Operation (OP) Code and a stressor.

s. Uncertainty Rating. A subjective rating ranging from 0 to 2 of the uncertainty attached to the data underlying the Exposure Rating and the Health Effect Rating. The higher the rating the greater the uncertainty of the estimate.

t. Upper Tolerance Limit (UTL). A limit below which we can assert with a specified level of confidence that a specified fraction of exposures will lie. For example, for a given exposure distribution, we may calculate the value below which we are 95 percent confident that 95 percent of exposures will lie. This value is sometimes called $UTL_{95\%,95\%}$.

u. Working Exposure Assessment. Classification of occupational exposures as "acceptable", "uncertain", or "unacceptable" based largely on whether and how the confidence intervals around the exposure estimate and the OEL overlap.

3. **SUMMARY.** The following is a summary of the exposure assessment strategy outlined in this chapter which is adapted from reference 4-2. Since this summary is very brief and the subject is complex, the industrial hygienist should read the full discussion in this chapter as well as reference 4-2.

a. Identify, based on existing information, scientific references, professional judgment, etc. SEGs for the various stressors present in the workplace.

b. Develop a best estimate of the SEG's 95 percentile exposure and the uncertainty associated with that estimate. If sufficient and satisfactory data are available, calculate the $UTL_{95\%,95\%}$ and use it as the estimate.

c. Identify the appropriate OELs for each exposure and the uncertainty associated with that estimate. Unless there is reason to believe otherwise, assume Navy OELs have high certainty.

d. If both the exposure estimate and the OEL have high degrees of certainty and the 95th percentile exposure estimate (e.g., $UTL_{95\%,95\%}$) is less than 50% of the OEL, the exposure assessment is considered "acceptable" and no routine exposure monitoring is recommended. At least qualitative reassessment is required when circumstances affecting exposure change and/or at the frequency specified in Appendix 8-B of reference 4-1.

e. If both the exposure estimate and the OEL have high degrees of certainty and 95th percentile exposure estimate (e.g., $UTL_{95\%,95\%}$) is greater than the OEL, the exposure assessment is considered "unacceptable" and exposures require control.

f. If the exposure estimate (e.g., $UTL_{95\%,95\%}$) is between 50% and 100% of the OEL, the exposure assessment category is "uncertain."

g. SEGs with "uncertain" exposures should be subjected to exposure monitoring to collect 6 to 10 random samples for further estimation of the SEG's exposure.

h. The additional data collected by exposure monitoring should be fed back into the basic characterization step to refine the exposure assessment and reclassify, if necessary, the SEG's exposure as "acceptable", "uncertain", or "unacceptable". Some SEGs will continue to have "uncertain" exposures and should be scheduled for annual exposure monitoring.

4. **EXPOSURE ASSESSMENT STRATEGY.**

a. Chapter 8 of reference (a) lists the six major steps of a functional occupational exposure assessment program. These are (1) basic characterization, (2) quantitative risk assessment and priority setting, (3) exposure monitoring, (4) interpretation and decision making, (5) recommendations and reporting, and (6) reevaluation. Reference 4-2 should be used as the basic reference for exposure assessment and its chapters address each of these six major steps as indicated in Table 4.1 below. The industrial hygienist is expected to consult reference 4-2 for a detailed explanation of the exposure assessment process.

Table 4.1 - Navy and AIHA Exposure Assessment Comparison

OPNAVINST 5100.23E Exposure Assessment Steps	**Corresponding Chapters in Reference 4-2**
Basic characterization	Chapter 3 - Basic Characterization and Information Gathering
Qualitative risk assessment and setting of priorities	Chapter 4 - Exposure Assessment: Establishing Similar Exposure Groups Chapter 5 - Exposure Assessment: Defining and Judging Exposure Profiles
Exposure monitoring	Chapter 6 - Further Information Gathering
Interpretation and decision-making	Chapter 7 - Quantitative Exposure Data: Interpretation, Decision Making, and Statistical Tools Chapter 8 - Health Hazard Control
Recommendations and reporting	Chapter 10 - Communications and Record Keeping
Reevaluation	Chapter 9 - Reassessment

b. The exposure assessment strategy of reference 4-2 represents a movement away from the traditional compliance assessment strategy toward a strategy that determines whether exposures are obviously "acceptable", are obviously "unacceptable", or for which there is insufficient information to make such a determination (i.e., "uncertain" exposures). The benefit is that information about the full exposure distribution is developed instead of just the upper extreme exposures and that sampling effort can be focused where it is most needed

(i.e., the "uncertain" exposures). This strategy promises to provide quality information with a minimum number of samples.

5. **BASIC CHARACTERIZATION.** Basic characterization is accomplished during the walkthrough survey and records reviews. Several items that affect occupational exposures (i.e., workplace, work force, stressors, controls) must be fully described and a review of existing data must be conducted. The objective of basic characterization is to identify combinations of process, personnel, and stressors that can be used to define groups of workers with like exposures that are referred to as a Similar Exposure Group (SEG).

a. Workplace. Description of the workplace involves documenting the processes or operations that are performed and inventorying the chemical, physical, and biological agents that are present in those processes or operations. Although production processes and operations are often well characterized, the industrial hygienist should not neglect to characterize the associated maintenance and repair work that often results in significant exposures.

(1) Processes and operations may be partially characterized by obtaining copies of process flowcharts or standard operating procedures. However, it is essential that the process or operation be observed in progress to fully understand the potential occupational exposures involved and to verify that the documents are an accurate reflection of the current process or operation. Informal discussions with workers, supervisors, engineers, and activity safety professionals are an important part of understanding the workplace.

(2) An inventory of chemical, physical, and biological stressors should be collected to allow classification according to their potential hazard. All routes of exposure (i.e., inhalation, ingestion, skin absorption) should be considered. As OELs for airborne exposures are reduced, the contribution from dermal exposure may become more significant.

b. Work Force. A combination of review of the activity's personnel classification system, worker/supervisor interviews, and direct observation are required to accurately characterize the work force.

(1) In describing the work force it is important that the industrial hygienist recognizes that identical job titles are not reliable predictors of similar exposures. For exam-

ple, exposures to welders vary greatly depending on the type of welding they do. A break-down of workers by department or shop may be useful but within a department or shop there is often a variety of processes (e.g., welding, abrasive blasting, grinding) or tasks (e.g., administrative, quality assurance, production, supervision) performed that result in different exposures. Obviously, departments and shops are structured for business management reasons not for occupational exposure considerations. A process-based or a task-based work force classification is often needed to arrive at the best selection of a SEG.

(2) Differences in work tasks and tempo between shifts also should be considered.

c. Stressors. Working from the list of stressors previously developed, the following information, as applicable, should be developed for each: quantity, relevant physical properties (e.g., vapor pressure, particle size distribution), health effects, and OELs. The applicable OEL for Navy use should be selected based on the policy in Chapter 16 of reference 4-1. The primary source of Navy OELs for chemical substances is OSHA's 1989 Final Rule PELs which are reproduced with all subsequent corrections in Appendix A of this manual. Care must be taken in determining what the appropriate exposure averaging time is, as this will determine which OEL is appropriate (e.g., Ceiling, STEL, 8-hour TWA). Although reference 4-2 discusses long-term average (LTA) OELs, which have averaging times greater than 8 hours, the Navy has not adopted such standards/guidelines. An exposure assessment cannot be done without an OEL.

d. Records Review. To complete the basic characterization, a review of relevant records must be performed. The types of records typically considered are: safety and health surveys, results of environmental monitoring, results of industrial hygiene monitoring, results of biological monitoring, personnel injury or illness reports, and engineering control assessments.

6. **QUALITATIVE RISK ASSESSMENT AND SETTING OF PRIORITIES.** This is defined by reference 4-2 as a three-step process where (1) the information gathered in basic characterization is used to define a SEG, (2) an exposure profile is determined for the SEG, and (3) the exposure profile for each group is judged to be either "acceptable", "uncertain", or "unacceptable".

a. Defining the SEG. A SEG may be defined by either observing the workplace and work force or by separating the work force based on the results of sampling data. The observational approach is more common since in many cases there is insufficient sampling data available to use that approach. In a mature industrial hygiene program, current and past exposure monitoring results are used to refine the definition of each SEG as necessary. Reference 4-2 recognizes six common bases for defining SEGs. The definition of every SEG includes one or more stressor(s). For Navy industrial hygienists, the initial definition of a SEG should be a combination of an OP Code and a stressor.

(1) Determining SEGs through observation.

(a) Combination of process/OP Code and stressor. In this scenario all workers involved in a process/OP Code are considered equally exposed. This may be because the stressor is evenly dispersed throughout the workroom or all process workers perform all tasks with essentially the same frequency and duration. In reality, this is not a common occurrence. For example, consider the combination of process/OP Code-mortar mixing/CON-006-03 and stressor-lime.

(b) Combination of process/OP Code, job title, and stressor. Addition of a worker's job title may help refine a SEG that is not adequately described by only process and stressor. However, the types of work tasks performed by persons having the same job title can vary greatly. Consider "laborers", a job title, working at a process who may perform different work tasks (e.g., bag dumping of raw materials, removal of finished product, clean-up of both) and may have very different exposures to the same stressor. For example, consider the combination of process/op Code-mortar mixing/CON-006-03, job title-laborer, and stressor-lime.

(c) Combination of process, job title, work task, and stressor. Including a specific work task in the SEG definition, in addition to process, job title, and stressor, more precisely defines the SEG. This separates the population into those performing a single work task with exposure to a specific stressor. For example, consider the combination of process/ OP Code-mortar mixing/CON-006-03, job title-laborer, work task-dumping bags of dry mortar into the mixer, and stressor-lime.

(d) Combination of process, work task, and stressor. Where job titles do not exist (e.g., small employ-

ers) or are not distinctive, job title may be eliminated from use in defining a SEG. This often occurs in manufacturing processes where work task alone keeps workers at a location with specific types of exposures. For example, consider the combination of process/OP Code-mortar mixing/CON-006-03, work task-dumping bags of dry mortar into the mixer, and stressor-lime.

(e) Work teams. When work teams share responsibilities and flexible duties, the significance of job title and work task in defining a SEG may be blurred. Reference 4-2 suggests that reasonable adjustments to defining a SEG may be made as follows:

1 If work locations are permanently assigned, the location is substituted for job title;

2 If workers change locations after working one day at a specific location, the work team is substituted for the job title and the work location is substituted for the work task; and

3 If workers rotate through the various locations during each day, the team is substituted for the job title and the work task may be ignored unless exposures will be assessed against a Ceiling or STEL OEL. When the latter is done, the work location is substituted for the work task.

(f) Non-repetitive work. Much of the work performed in the Navy is batch processes, job shop-type work, or research and development. People performing this type of work are difficult to categorize into SEGs. Professional judgment must be used in establishing SEGs for such work or pursuing alternate exposure assessment strategies. One strategy is to assess compliance with OELs by assessing worst case exposures. Another strategy is to consider each project as a distinct process and define SEGs for each project. This leads to a large exposure monitoring effort since many short-term projects must be sampled. Reassessment (discussed later in this chapter) may provide data to refine the definition of SEGs for non-repetitive work that may reduce sampling after initial data is collected. Again, such situations are best addressed by industrial hygiene professionals with substantial experience that provides a strong basis for accurate professional judgment.

(2) Determining SEGs by sampling. Although not recommended in most cases, due to the high cost in terms of labor

and analysis and the difficulty in executing a massive sampling campaign, SEGs may be defined by sampling results. Since one of the primary reasons for defining SEGs is to reduce the sampling requirements, it is best done by observation rather than sampling. If sampling is to be used, samples should be collected at random and multiple samples must be collected for each individual to be able to calculate the within-worker and between-worker variability. When sufficient data is available, the rule of thumb is that within a properly defined SEG the 97.5 percentile exposure should be approximately twice the 2.5 percentile exposure. In other words, 95% of the exposures should span a doubling of concentration. As the 97.5 percentile exposure recedes from the OEL, maintaining this exposure spread in a SEG becomes less critical. For example, a spread of a factor of four between the 2.5 percentile and 97.5 percentile exposures is of little consequence if the 97.5 percentile exposure is still less than one tenth of the OEL.

b. Determining the SEG's exposure profile. Establishing an exposure profile consists of obtaining the best exposure estimate and then categorizing that estimate by assigning an exposure rating.

(1) Estimating the exposure should involve a combination of quantitative and qualitative information. Exposure estimates should be conservative to avoid errors that would lead to a conclusion that an exposure is acceptable when, in fact, it is not. Initially, most profiles will be more qualitative because at this stage in the exposure assessment process, sufficient exposure monitoring has not occurred which is one reason an assessment strategy is being pursued. The following information sources rely on both qualitative and quantitative information:

(a) Monitoring data. The industrial hygienist may draw upon his personal knowledge of exposures from the same or similar process with which the industrial hygienist is familiar. The industrial hygienist should consult the Navy Occupational Exposure Database (NOED), maintained at the Navy Environmental Health Center, for sampling results of the same operation at one or more Navy activities. The industrial hygienist should consult the scientific literature for published data. A limited number of screening measurements may be made to add to the available data or confirm that the current process appears to correspond to data developed by others.

(b) Surrogate data. When more relevant data is not available, exposure data from another stressor with similar physical properties and used in a similar or the same process may be considered. Such data is sometimes used to estimate the airborne concentration of other chemicals in a mixture when the airborne concentration of only one of the chemicals is known. Exposure data from another process using the same stressor may also be considered. Such data must be tempered with good professional judgment.

(c) Modeling. Exposures may be estimated based on models that consider the chemical and physical properties of a stressor along with the effect of existing controls and estimated generation and removal rates. When used, model parameters should be selected to arrive at a conservative estimate of exposure. The industrial hygienist should remember that all models are imperfect and must be used with a critical eye and sound professional judgment. Modeling based on environmental release data from a process can also help estimate exposures.

(2) Assigning an exposure rating.

(a) Exposure ratings for chemical stressors with Ceiling, STEL, and 8-hour TWA OELs and for physical stressors (e.g., noise) with established NAVOSH standards, as defined in Chapter 16 of reference 4-1. The exposure rating categories that should be used for these stressors are similar to those listed in Table 5.2 of reference 4-2 and are explained in Table 4.2 below. Exposure ratings should be assigned assuming that no personal protective equipment is worn. For chemical stressors, Table 4.2 addresses only airborne exposures, however, if dermal exposures are expected to be a significant contribution to overall exposure, adjustments to the exposure rating should be made.

Table 4.2 - Exposure Rating Categories
Based on an Estimate of the 95th Percentile Exposure*

Exposure Rating Category	**Relation of the Estimate of the 95th Percentile Exposure to the OEL****
4	>5% exceedance of the OEL (i.e., 95th percentile exposure estimate > OEL)
3	>5% exceedance of 50% of the OEL (i.e., 95th percentile exposure estimate lies between 50% the OEL and the OEL)

Exposure Rating Category	Relation of the Estimate of the 95th Percentile Exposure to the OEL**
2	>5% exceedance of 10% of the OEL (i.e., 95th percentile exposure estimate lies between 10% of the OEL and 50% of the OEL)
1	Little to no exceedance of 10% of the OEL (i.e., 95th percentile exposure estimate is virtually always less than 10% of the OEL)

* Per reference 4-2

** If a sufficient number (e.g., 6 to 10) of exposure measurements are available for the SEG and they meet the requirements for randomness, stationary population and normal or log-normal distribution, use the $UTL_{95\%,95\%}$ as the estimate of the 95th percentile.

(b) Exposure ratings for chemical stressors with LTA OELs. Although reference 4-2 provides a table of exposure ratings for chemical stressors with LTA-OELs, LTA-OELs have not been adopted for Navy use and use of that table is not recommended.

(c) Exposure ratings for stressors without a NAVOSH standard. Exposure ratings require that an OEL exist. In the rare case where a NAVOSH standard as defined in Chapter 16 of reference 4-1 does not exist, the industrial hygienist should consult with the Navy Environmental Health Center to determine what the appropriate "working" OEL should be.

c. Comparing the SEG's exposure profile to the OEL. By comparing the exposure profile to the OEL, one may assign an Exposure Rating. This requires considering how much uncertainty exists about whether the OEL is adequately protective and the exposure estimate is accurate. The Exposure Rating may be used to assign SEGs a Working Exposure Assessment of "acceptable", "uncertain", or "unacceptable." The idea is to determine those exposures for which there is high, low, or unknown potential for exceeding the OEL. Those categories correspond to a Working Exposure Assessment of "unacceptable", "acceptable", or "uncertain" risk of exceeding the OEL.

(1) Considering the uncertainty around the OEL. For NAVOSH standards, one should assume that there is a high degree of certainty that the NAVOSH standard is correctly set and, therefore, adequately protective (i.e., low uncertainty and a small confidence interval). The industrial hygienist should consider whether recent scientific evidence increases

the uncertainty around a NAVOSH standard and compensate appropriately in the exposure assessment. One indicator of uncertainty is if more recent OELs are lower than the existing NAVOSH standard.

(2) Considering the uncertainty around the exposure estimate. While developing the exposure profile, the industrial hygienist should have developed at least a subjective estimate of the uncertainty around the exposure estimate. The industrial hygienist is reminded that all exposure models are imperfect.

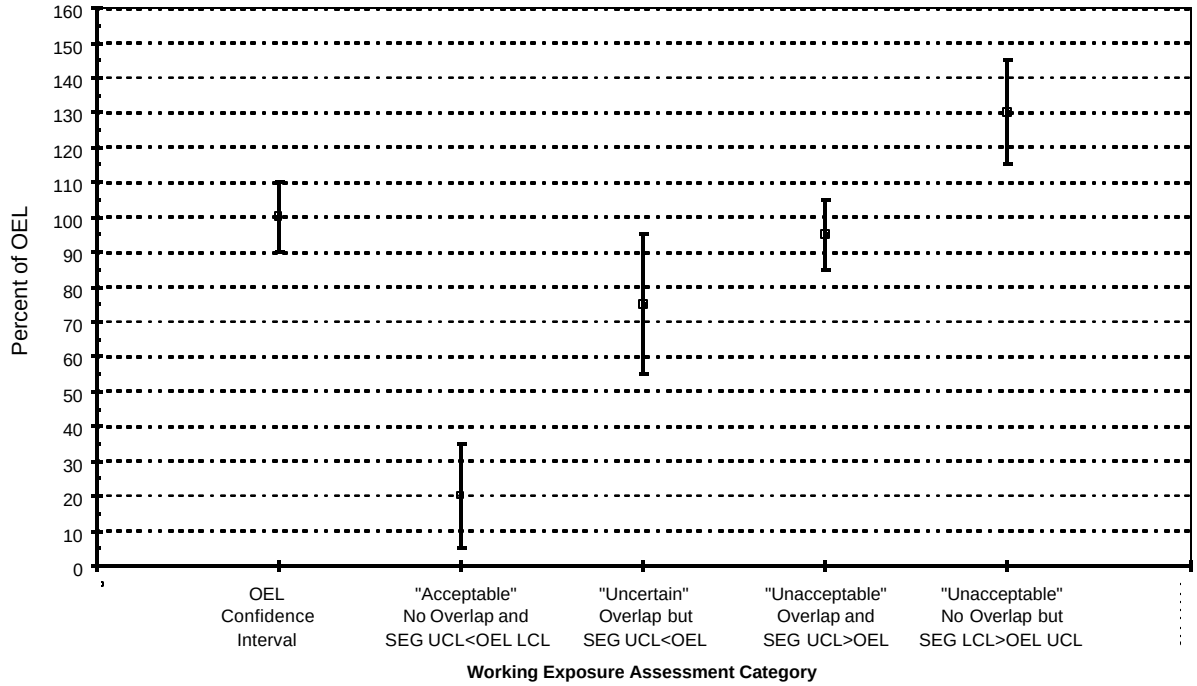
(3) Making the Working Exposure Assessment. In making the Working Exposure Assessment, the industrial hygienist must decide whether and how the subjective and/or objective confidence intervals around the exposure profile and the OEL do or do not overlap. That overlap (see Figure 4-1 below) or lack of overlap determines the Working Exposure Assessment. When there is no overlap the exposure is clearly either acceptable or unacceptable depending on whether it is above or below the OEL. When there is overlap, the Working Exposure Assessment will be either uncertain or unacceptable. For Navy OELs which are mainly 8-hour TWAs, STELS, and Ceiling values, the target parameter is the 95^{th} percentile value and the uncertainty is described by the 95% confidence upper tolerance limit aroung the 95^{th} percentile value (i.e., $UTL_{95\%,95\%}$). Assuming that NAVOSH standards have a high degree of certainty, Working Exposure Assessments may be assigned to the Exposure Ratings of SEGs as follows:

(a) Acceptable exposures. Exposures where there is no overlap of the exposure profile and OEL confidence intervals and the lower confidence limit (LCL) of the OEL is greater than the upper confidence limit (UCL) of the SEG's exposure profile. A SEG with an Exposure Rating of 1 or 2 and with high certainty about the exposure profile and the OEL may be considered an "acceptable" exposure. The industrial hygienist concludes that no adverse health effects from existing exposures are expected since the exposures are not expected to exceed 50% of the OEL.

(b) Uncertain exposures. Exposures where there is overlap of the exposure profile and OEL confidence intervals. A SEG with an Exposure Rating of 3 may be considered an "uncertain" exposure since the upper tail of its exposure profile may approach the OEL. The available information is unable to predict with certainty whether overexposure will occur.

(c) Unacceptable exposures. There are two possibilities. First, there is no overlap of the exposure profile and OEL confidence intervals and the upper confidence limit (UCL) of the OEL is less than the lower confidence limit (LCL) of the SEG's exposure profile. Second, there is overlap of the exposure profile and OEL confidence intervals and the estimate of the exposure's 95th percentile UCL (e.g., $UTL_{95\%,95\%}$) is greater than the OEL. A SEG with an Exposure Rating of 4 represents an "unacceptable" exposure. The exposures of these SEGs are expected to exceed the OEL more frequently than is acceptable and need to be controlled.

Figure 4.1 - Effect of OEL and SEG Confidence Interval Overlap on Exposure Assessment



7. **EXPOSURE MONITORING**. The exposure monitoring plan should be constructed using the following strategy. The industrial hygienist is encouraged to use professional judgment as appropriate to identify additional SEGs for monitoring as dictated by local circumstances rather than be driven solely by the process described below. Conversely, the industrial hygienist should not feel compelled to expand monitoring beyond those SEGs selected by the process if professional judgment does not identify additional SEGs.

a. Deciding which SEGs need exposure monitoring. The Exposure Rating categories previously developed should be used as a basis for deciding which SEGs require exposure monitoring. Using the "Working Exposure Assessment" categories of "acceptable", "unacceptable", and "uncertain" described above, the industrial hygienist will want to target "uncertain" exposures. Industrial hygienists should use sound professional judgment to adapt the recommendations below to local circumstances.

(1) Exposure Rating 1 - Little to no exceedance of 10% of the OEL (i.e., 95th percentile exposure estimate is virtually always less than 10% of the OEL) - SEGs in this category are not candidates for exposure monitoring as long as factors that affect exposures do not change.

(2) Exposure Rating 2 - >5% exceedance of 10% of the OEL (i.e., 95th percentile exposure estimate lies between 10% of the OEL and 50% of the OEL) - SEGs in this category are not usually candidates for exposure monitoring as long as factors that affect exposures do not change. However, consideration should be given to scheduling 5% to 10% of these SEGs for exposure monitoring to verify the accuracy of the exposure estimate.

(3) Exposure Rating 3 - >5% exceedance of 50% of the OEL (i.e., 95th percentile exposure estimate lies between 50% the OEL and the OEL) - All SEGs in this category should be scheduled for exposure monitoring to provide sufficient data to classify each SEG as either "acceptable" or "unacceptable." Even with additional sampling the exposure profiles of some SEGs will continue to be in this exposure rating category and they will be subject to annual exposure monitoring unless controls or process modifications change their exposure profiles.

(4) Exposure Rating 4 - >5% exceedance of the OEL (i.e., 95th percentile exposure estimate > OEL) - SEGs in this category should be controlled. Exposure monitoring may be conducted to determine appropriate personal protective equipment (PPE) requirements if interim controls are used. Exposure monitoring also may be indicated to verify the need for controls when the cost of controls is high, for legal reasons or to provide a basis for assessing the benefit of controls that will be installed.

b. Assigning a Health Effects Rating to a SEG. Since different stressors produce different health effects it is logical to use the gradation in health effects to help deter-

mine priorities for intervention. There are a number of different health effects rating systems, only one of which will be proposed here. The health effects categories presented in Table 4.3 below are those described in reference 4-2.

Table 4.3 - Health Effects Ratings*

Health Effects Category	Health Effect
4	Life-threatening or disabling injury or illness
3	Irreversible health effects
2	Severe, reversible health effects
1	Reversible health effects of concern
0	Reversible health effects of little concern or no known or suspected adverse health effects

* Per reference 4-2

Navy industrial hygienists must use professional judgment and available reference material in assigning a Health Effect Rating to a stressor. For chemical stressors, the procedures specified in the National Paint and Coatings Association's (NPCA) Hazardous Materials Identification System (HMIS) may be helpful. The NPCA HMIS system is completely different from the DoD Hazardous Materials Information System (HMIS) and the two should not be confused nor are they interchangable. Reference 4-2 should be consulted for a more detailed discussion. Keep in mind that this rating is being used only to prioritize SEGs with exposures below the OEL for exposure monitoring to determine if the Working Exposure Assessment was correct. All SEGs in the "uncertain" category should be monitored. Therefore, although current processes for assigning a Health Effects Rating are imprecise, the consequence of rating an exposure one category lower is not severe, since it will only delay not prevent exposure monitoring, unless it is assigned a Health Effect Rating of 0.

c. Determining the Health Risk Rating. The Health Risk Rating will be most useful for prioritizing exposure monitoring of SEGs assigned a Working Exposure Assessment of "uncertain." However, the Health Risk Rating can be used to rank the overall health risk for different SEGs. By constructing a table with columns for each Exposure Rating category and rows for each Health Effect Rating category one can compute a Health Risk Rating for each exposure to a stressor by multiplying the Exposure Rating times the Health Effect Rating, as

in Table 4.4 below. This is the approach taken in reference 4-2.

Table 4.4 - Health Risk Ratings*

		Exposure Rating / Working Exposure Assessment			
		1/ Acceptable	2/ Acceptable	3/ Uncertain	4/ Unacceptable
Health Effect Rating	4	4	8	12	16
	3	3	6	9	12
	2	2	4	6	8
	1	1	2	3	4
	0	0	0	0	0

* Per reference 4-2

The higher the Health Risk Rating number, the higher the risk and the higher the priority for exposure monitoring. Obviously, exposures with a Health Effect Rating of zero (0) do not represent a significant health risk nor merit exposure monitoring and are often not shown in a Health Risk Rating table.

d. Prioritizing SEGs for exposure monitoring. In the simplest case, the Health Risk Rating can be used as a method for prioritizing SEGs for exposure monitoring. When a large number of SEGs all have the same Health Hazard Rating, it may be desirable to create additional rankings based on the uncertainty of estimating the Exposure Rating and the Health Effect Rating. This process is a follows:

(1) Determining the Uncertainty Rating. The industrial hygienist may make a subjective determination of the uncertainty associated with both the Exposure Rating and the Health Effect Rating and categorize it as either "highly uncertain", "uncertain", or "certain." Those categories are descirbed in Table 4.5 below as they are in reference 4-2.

Table 4.5 - Uncertainty Rating Categories*

Uncertainty Rating	**Description**
2	**Highly Uncertain** - Sufficient information was not available to confidently describe the exposure and/or health effect.

Uncertainty Rating	Description
1	**Uncertain** - The health effect information is adequate but, although sufficient exposure information was available to make an Working Exposure Assessment, additional exposure monitoring is required to make a final exposure assessment.
0	**Certain** - Both the stressor's exposure profile and health effects are well-understood. The IH has high confidence that both exposure and effect ratings are accurate.

* Per reference 4-2

(2) Computing the Exposure Monitoring Priority. The industrial hygienist may make adjustments to the Health Risk Rating for uncertainty by multiplying the Health Risk Rating by the Uncertainty Rating to arrive at the Exposure Monitoring Priority. The Exposure Monitoring Priority ranges from 0 to 32 with a higher number representing a higher priority for exposure monitoring. Obviously, SEGs where the Uncertainty Rating is zero have a zero priority for exposure monitoring, since this means the industrial hygienist considers that all estimates used in the assessment are very accurate.

e. Mechanics of Exposure Monitoring.

(1) General. Usually, exposure monitoring is performed for three reasons: profiling, compliance, and diagnostic. Exposure data may be required to establish an exposure profile or to determine if an established exposure profile is still valid. This type of monitoring relies on statistically valid random sampling. Monitoring may be conducted to determine if exposures are in compliance with a Navy OEL. This type of monitoring usually focuses on "worst case" scenarios. Stressor levels may be measured to provide information used to control the exposure (e.g., identifying stressor "hot spots"). The following discussion covers monitoring as it related to exposure profiles.

(2) Basic monitoring considerations. The following factors should be considered when deciding how and when exposure monitoring should be conducted:

(a) Exposure pathway. The industrial hygienist should select a monitoring method that is appropriate for the significant exposure pathways (i.e., inhalation, skin absorption, or ingestion).

(b) Sampling duration. It is important that the duration of monitoring be an appropriate mirror of the averaging time of the OEL for that stressor (e.g., full-shift monitoring for 8-hour TWAs, 15 minute sample duration for STELs).

(c) Seasonal variations. If seasonal changes in working conditions (e.g., doors shut in the winter and open in the summer) will affect exposures, sampling should address those differences. Either sampling should cover all seasons or each season's exposure should be documented.

(d) Differences between shifts. If exposures are expected to differ between shifts either different shifts should be different SEGs or all shifts should be sampled.

(3) How many samples? The industrial hygienist should collect 6 to 10 samples from randomly selected members of a SEG. Six samples is the minimum needed to provide reasonable certainty and more than 10 samples provides only a small amount of increased certainty per extra sample collected.

(4) Random sampling for profiling. The 6 to 10 samples recommended above must be collected randomly to allow statistically valid inferences to be drawn. Random selection gives the best chance of documenting variability in the population of all exposures. To randomly select the persons to be sampled and the dates and shift on which they will be sampled the following actions should be followed:

(a) Determine the time period over which sampling will be conducted (e.g., a year, a season, a month). Very long time periods (e.g., a year, several months) delay the interpretation of the data and risk a change in the exposures during the sampling campaign. Very short time periods (e.g., one week) risk not revealing the true variation of exposures.

(b) Randomly choose sampling dates from the time period selected. If the process in question does not occur frequently, it may be necessary to sample every time it occurs until the required number of samples has been collected. One must recognize that this assumes the exposure distribution is stationary (i.e., exposure variables such as weather, equipment, engineering controls, and operator skill do not change). Although a stationary distribution may not exist for infrequently performed processes, sampling each occurrence is often the only practical strategy due to the small number of workers involved in these processes. If the number of similarly ex-

posed individuals involved in an infrequent process is large enough (i.e., at least six) then sampling all the individuals or a statistically valid random sample of the individuals in the SEG is a good strategy.

(c) If applicable, randomly choose the shifts to be sampled on each of the sampling dates.

(d) Randomly choose the workers from the SEG that will be sampled on a given shift on a given day. This will probably have to be done within a few days of the sampling date since work schedules change frequently.

(e) If STEL or Ceiling samples are being collected, randomly select the high-exposure tasks that occur during the shift and day previously chosen for sampling.

f. Exposure monitoring to fulfill requlatory requirements. While constructing an exposure monitoring plan, the industrial hygienist must ensure that samples required to comply with regulatory requirements (e.g., lead standard) are collected. When possible, sampling should be arranged to allow samples to serve the dual purpose of meeting regulatory requirements and providing random data points for statistical inferences.

8. **INTERPRETATION AND DECISION-MAKING**. Once 6 to 10 random samples have been collected, the data needs to be analyzed and decisions made. Analysis must be performed on data with the same averaging time (e.g., all 8-hour TWA samples, all STEL samples). That analysis should be performed in the following manner:

a. Dealing with results below the analytical limit of detection (LOD).

(1) 8-hour TWA sampling data. Navy industrial hygienists should use IHIMS to calculate 8-hour TWAs and sample data statistics. By using IHIMS, Navy industrial hygienists should rarely have to deal with 8-hour TWA results below the LOD. IHIMS automatically adjusts results that are less than the LOD prior to calculating the 8-hour TWA. This process is referred to as censoring. When censored data is used to calculate the 8-hour TWA, the resulting TWA is not considered to be censored nor is it expressed as "less than" the calculated value. The few exceptions to this are TWAs that were calculated by early versions of IHIMS and TWAs in the single-digit microgram per

cubic meter range which is at the lower limit of IHIMS' data field size. Beryllium and cadmium are the most common examples of stressors which may have "less than" values for 8-hour TWAs in IHIMS due to the low concentrations usually documented.

(2) STEL and Ceiling value data. STEL and Ceiling value data with results below the LOD are stored in IHIMS as "less than" values since a TWA is not calculated. Therefore, Navy industrial hygienists will commonly encounter STEL and Ceiling value data sets with results that need to be censored prior to analysis.

(3) Censoring techniques. The following actions are recommended for preparing data sets with "less than" values for statistical anaysis. Remember that once censored the censored value no longer carries the "less than" qualifier.

(a) If 50% or more of the results are less than the limit of detection (LOD), the industrial hygienist should adjust the sampling protocol to obtain data that is greater than the LOD. Alternatively, contact the Navy Environmental Health Center, Industrial Hygiene Directorate, Mr. L. Turner, (757) 462-5517, for assistance in analyzing such data.

(b) If less than 50% of the results are "less than" the limit of detection (LOD), such values may be censored by assigning them values of 70% of the LOD, if the sample Geometric Standard Deviation (GSD) is <3, and 50% of the LOD, if the sample GSD is ≥ 3, per reference 4-2. Currently, IHIMS censors "less than" results by dividing the result by the square root of 2 . For consistency, Navy industrial hygienists should divide "less than" results by the square root of 2 when censoring data outside of IHIMS.

(4) Effect of using censored data for statistical analysis by IHIMS. Note that the higher the percentage of censored values in the sample the more uncertain statistical analysis of the data becomes. The algorithm used by IHIMS to conduct statistical analysis of censored data sets will not perform the analysis, if the following conditions are not satisfied:

(a) There must be at least 3 or more uncensored values in the data set.

(b) If the sample size is less than 20, no censored values are allowed.

(c) If the sample size is greater than or equal to 20, no more than 80% of the values may be censored.

b. Verify that the exposure monitoring data are log-normally distributed. Use the Shapiro Wilk test (sometimes referred to as the W-test) to determine if the exposure monitoring data is lognormally distributed. A log-probability plot will also check for log-normality.

(1) If the data is not log-normal, either the SEG is not correctly defined or the exposure population is not stationary. In that case, the SEG must be redefined. This does not mean discard the data, rather it means regroup the data into two or more SEGs. For example, if the exposure population was not stationary, separate the sample results into two groups, one for the samples taken before the exposures changed and one for the samples taken after the exposures changed. In that case additional samples will have to be taken and added to the group containing samples after the exposure changed to provide a total sample size of 6 to 10 samples. After that is done return to the beginning of this paragraph (i.e., paragraph 8) and begin the data analysis with this new data set.

(2) If the data is log-normally distributed continue the data analysis.

c. Verify that the exposure population was stationary. If the population of exposures changed during exposure monitoring, the monitoring results cannot be interpreted as a whole. Plot the results sequentially as they were taken and look for trends either upward or downward. If a trend is evident, the data should be separated into two or more groups based on noticeable changes in exposure over time. If no trends are apparent, assume the eposure population is stationary and continue the data analysis.

d. Determine the descriptive statistics of the data. Calculate the sample median, range, maximum value, minimum value, arithmetic mean (using the minimum variance unbiased estimate [MVUE]), and standard deviation. From the log-probability plot of the data obtain the geometric mean (50%ile value) and the GSD (84%ile value minus the 50%ile value).

e. Determine if the SEG is correctly defined. If the variability of the data is large (i.e., GSD>3) this may be an indication that either the SEG is not properly defined or the process is out of control. The industrial hygienist should

determine if this is the case and, if so, adjust the definition of the SEG to decrease the variability and collect any additional exposure monitoring data required.

f. Estimate the exposures in the upper tail. For determining what Exposure Rating category describes a SEG, focus on the 95^{th} percentile exposure in the upper tail. These upper tail values are used to assess exposures that are compared to 8-hour TWA OELs, STEL-OELs, and Ceiling-OELs which are what the Navy currently uses. The statistical parameters mentioned below are calculated the Industrial Hygiene Information Management System (IHIMS) starting with Version 1.12. Industrial Hygiene Departments should update to that version of IHIMS and use it to calculate these parameters. Alternatively, the Industrial Hygiene Statistics Spreadsheet supplied with reference 4-2 may be used. This is an Excel® spreadsheet and requires the user to have Microsoft Excel® installed on their computer to run it. Another alternative is to calculate parameters using the formulas, tables, and figures in reference 4-2.

(1) Determine the 95^{th} percentile exposure

(2) Determine the $UTL_{95\%,95\%}$.

(3) Determine the exceedance fraction/probability of noncompliance.

(4) Determine the one-sided 95% upper confidence limit ($UCL_{1,95\%}$) for the exceedance fraction/probability of noncompliance.

g. Refining a SEG's Working Exposure Assessment. The industrial hygienist is reminded that statistics are an aid to decision making and that the ultimate decision should be based on a combination of professional judgment and statistics. The results of exposure monitoring are fed back into the exposure assessment process at the "basic characterization" step described in paragraph 5. The following are guidelines for revising the Working Exposure Assessment based on exposure monitoring results of 6 or more randomly collected samples when compared to a Navy OEL which is an 8-hour TWA, a STEL, or a Ceiling value:

(1) If the $UTL_{95\%,95\%}$ is greater than the OEL, the Working Exposure Assessment may be “unacceptable”. Professional judgment along with all available information should be used by the industrial hygienist to make a final determination.

Significant additional exposure monitoring should be conducted to better quantify the SEG's exposure distribution, if the operation is not selected for control actions. Such processes should receive a high priority for additional information gathering.

(2) If the $UTL_{95\%,95\%}$ is less than or equal to 50% of the OEL, the Working Exposure Assessment is "acceptable" and the operation may be monitored at the discretion of the industrial hygienist as necessary to ensure that the exposure profile has not changed.

(3) If the $UTL_{95\%,95\%}$ is greater than 50% of the OEL but less than the OEL, the Working Exposure Assessment is "uncertain" and this SEG should be scheduled for annual exposure monitoring as long as it remains "uncertain." Due to the small initial sample size (i.e., 6 to 10) a UTL95%,95% less than 50% of the OEL may not be achievable from the first round of exposure monitoring. This depends on the GM and GSD of the exposure population. The lower the GM is as a percentage of the OEL and the lower the GSD is, the fewer the number of samples that are needed to satisfy the acceptance criteria.

h. Control of "unacceptable" occupational exposures.

(1) Prioritizing SEGs for control of "unacceptable" occupational exposures. The industrial hygienist may use the Health Risk Rating in Table 4-4 as a rough index of control priority. SEGs with a Health Risk Rating of 8 or higher are candidates for control. A larger Health Risk Rating implies a higher priority for control. The industrial hygienist should also consider the uncertainty of the exposure estimate and the OEL in recommending priorities for control.

(2) Actions after controls are implemented. After occupational exposure controls are implemented, the SEG's Working Exposure Assessment should be changed to "uncertain" and exposure monitoring should be conducted as described in this chapter. This new information should be used to update the exposure assessment starting with the basic characterization step in paragraph 5.

9. **RECOMMENDATIONS AND REPORTING**.

a. Reports. Reports of industrial hygiene surveys are provided to the appropriate customer(s) in the manner outlined in Chapter 2 of this document.

b. Exposure Assessments. Exposure assessments must be well documented by the industrial hygienist and retained in the industrial hygienist's files but the details of the assessment should not be reported to the customer due to the volume of material involved. Instead, a summary chart showing the SEGs and the final exposure assessment category assigned would be appropriate. In the current report format, the Working Exposure Assessment category is included in the narrative.

10. **REEVALUATION**.

a. Qualitative reevaluation. Although SEGs with "acceptable" Working Exposure Assessments are not candidates for routine exposure monitoring, they require at least a qualitative reevaluation be conducted at least at the frequency stated in Appendix 8-B of reference 4-1. Any changes in the OEL, the workplace or the work force that may affect exposures should be evaluated before or at the time it occurs. Information from the reevaluation should be fed back into the Basic Characterization step of the exposure assessment process (i.e., paragraph 5 of this document) and all the elements of the exposure assessment should be updated.

b. Quantitative reevaluation. Although not required, a program to validate Working Exposure Assessments of "acceptable" with exposure monitoring data is recommended for 5% to 10% of these SEGs. Such data collection should not interfere or compete with the more important tasks of exposure monitoring of "uncertain" exposures or control of "unacceptable" exposures. Information from the reevaluation should be fed back into the Basic Characterization step of the exposure assessment process (i.e., paragraph 5 of this document) and all the elements of the exposure assessment should be updated.

11. **REFERENCES**.

4-1 OPNAVINST 5100.23 Series

4-2 AIHA: *A Strategy for Assessing and Managing Occupational Exposures,* edited by J. R. Mulhausen and J. Damiano, Fairfax, VA: AIHA Press, 1998.